

## Blood-Stream Infection (CDC)

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**From:** Laura Andrade [mandrade29@cox.net]

**Sent:** Thursday, December 03, 2009 9:17 PM

**To:** Blood-Stream Infection (CDC)

**Subject:** public comment, Draft Guidelines for the Prevention of Intravascular Catheter Related Infections

Unfortunately my previous email (sent at 4:00 PM [PST] contained a couple of typos). I have corrected them here. If possible, I would like you to disregard/delete my previous email in favor of the following revised comment.

Thank you,  
Laura Andrade

My name is Laura Andrade, and I am a senior research analyst for a health technology research and consulting company. In response to your request for public comment for the currently proposed Draft Guidelines for the Prevention of Intravascular Catheter Related Infections, I would like to express my concern over the following recommendation:

“When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection.”

I suggest that recommendation be removed from the final guidelines. There is significant potential for confusion due to poorly defined terms. And, most importantly, the quality of evidence cited in support of this recommendation is insufficient for any definitive conclusions.

### Poorly defined terms:

The terms “split septum” and “mechanical valve,” within needleless connector technology, can mean different things to different people. For example, split-septum needleless devices can be the traditional membrane with a pre-cut slit or they can be a reverse split septum, modified split septum, or swab-able surface membrane. In addition, there are devices that have both a luer activation and a split septum.

Unfortunately the term “mechanical valve” can be equally misleading. To some, “mechanical valve” has a broad definition, and it includes any device with any internal mechanism. This would include both simple and complex mechanical valves. To others, the term “mechanical valve” refers only to the more complex mechanical mechanisms. (In general, simple mechanical valves, like a luer activated device with an internal cannula, have a fairly direct, non-turbulent fluid path. Complex mechanical valves, such as a positive pressure device, have an indirect and more turbulent fluid path.)

### Lack of quality evidence:

The evidence from the studies (Maragakis et al., 2006; Field et al., 2007; Rupp et al., 2007; Salgado et al., 2007) cited to support this recommendation is of poor quality and is insufficient to tell us anything conclusive about “split septum” or “mechanical valve” devices. These studies were not designed as controlled, comparative studies.

All of the studies had important limitations. For example, studies did not report comprehensive or detailed controls to reduce bias; some studies included heterogenous patient groups; few studies described any training with the needleless connectors; some studies failed to describe patients lost to follow-up; some studies did not report patient numbers or had low patient numbers; some studies had unclear or absent reporting of antibiotic use and of the number of catheter days between groups.

Most studies did not include any analysis of nursing procedures or staffing issues, which are known to have an effect on catheter-related bloodstream infection (CRBSI) rates.

In regard to conclusions about "split septum" or "mechanical valve" devices, these studies have far too many variables to allow definitive conclusions.

- One characteristic that the “more desirable” devices in these studies have in common is the split septum. However, the “less desirable” devices in the studies also have either a split septum, reverse split septum, or a modification of the split septum (all have a flat, swab-able membrane surface). Based on these studies, it is not possible to conclude that the “split septum valve” is associated with lower CRBSIs.
- Another noticeable characteristic of the better performing devices in these four studies is that they generally have a more open and less turbulent flow path, compared with the positive pressure devices. This characteristic is not noted in the new draft guideline.
- Although these studies do suggest that complex mechanical mechanisms (particularly positive pressure devices) may be associated with higher CRBSIs, again, it is not possible to definitively conclude that from such weak evidence.

In conclusion, the available evidence is insufficient to conclude that “the split septum valve is preferred over the mechanical valve due to increased risk of infection” at this time. The relationship between needleless devices and CRBSI rates remains uncertain. No single needleless device design, model, or brand is consistently associated with unusually high (or low) CRBSI rates. Unfortunately the available published evidence isn’t strong enough to guide clinical decisions about what needleless connector to use. Several factors related to the design of needleless devices have been suspected of increasing CRBSI risk, but none has been proven to be a direct cause of infection. Until conclusive evidence becomes available to differentiate among the different devices, healthcare workers and institutions must continue to monitor their chosen needleless devices, evaluate device-related outcomes and CRBSI rates, and attempt to better address the possibility of human error.

I suggest that this recommendation be removed from the final guidelines until quality evidence from well design, controlled studies is available so that accurate, well-defined recommendations can be made.

Thank you for your time and consideration.

Sincerely,  
Laura Andrade